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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
10/087,573	02/28/2002	Theodorus Petrus Maria Schetters	I 2001.004 US	3895

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EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	6

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/087,573	SCHETTERS ET AL
	Examiner	Art Unit
	Padmavathi v Baskar	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 23-63 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4. ☐ Interview Summary (PTO-413) Paper No(s).
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Other: .

Election/Restrictions

1. Applicant's preliminary amendment filed on 2/28/02 has been entered. Claims 1-22 have been canceled. New claims 23-63 have been entered

2. Restriction to one of the following groups of invention is required under 35 U.S.C. 121:

I. Claims 23-31 and 36-39 drawn to isolated Babesia canis nucleic acid encoding 15kD antigen (SEQ.ID.NO: 2), vaccine and a kit for detection of infection classified in class 536, subclass 23.7.

II. Claims 32-35 drawn to Babesia canis 15kD antigen (SEQ.ID.NO: 2), classified in class 530, and subclass 350.

III. Claim 40 drawn to a vaccine comprising antibody to 15kD antigen, classified in class 530, subclass, 388.6.

IV Claims 44-52 and 57-60 drawn to isolated Babesia canis nucleic acid encoding 32kD antigen (SEQ.ID.NO: 4) and a vaccine composition, classified in class 536, subclass 23.7.

V Claims 53-56 and 62 drawn to Babesia canis 32kD antigen (SEQ.ID.NO: 4), vaccine and a kit for the detection of antibodies, classified in class 530, subclass 350.

VI. Claim 61 and 63 drawn to a vaccine comprising antibody to 32kD antigen and a kit for the detection of antigen, classified in class 530, subclass 388.6. 3

VII. Claim 41 is drawn to a diagnostic test using nucleic acid classified in class 435, subclass 6.

VIII. Claim 42 is drawn to a diagnostic test using antigen classified in class 435 subclass 7.22

3 The inventions are distinct, each from the other because of the following reasons:

Group I and IV are directed to two different nucleic acid sequences encoding 15kD and 32 kD antigens, which are nucleic acids, Groups II and V, are directed to 15kD and 32 kD antigens, which are made of amino acids. Invention III and VI are drawn to a vaccine composition comprising two different antibodies to 15kD and 32 kD antigens, which are distinct from Inventions I /IV and II/V since antibodies have an inherent affinity, avidity, and specificity that a DNA or a simple protein is not capable of expressing. These products are different to each other structurally, biochemically and functionally and are drawn to patentably distinct inventions which have materially different physical and chemical properties and structures as represented by their divergent sequences, molecular weights. Inventions VII, VIII and IX are drawn to diagnostic tests for detecting infection, antibody or antigen using nucleic acids or amino acids or antibodies. These diagnostic methods are different to each other in utilizing different products that are different to each other structurally, biochemically and functionally.

4. Inventions 1 and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different nucleic acids encoding structurally different 15kD and 32kD antigens. Therefore. where structural identity is required. such as for hybridization or expression, the different sequences have different effects. Thus, each nucleic acid encoding different antigen is unique and patentably distinct since each nucleic acid encodes different antigen which has different structure as represented by different sequences

products appear to constitute patentably distinct inventions. Therefore, each invention is deemed to constitute independent and distinct invention within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

5. Invention I is related to inventions VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group I can be used to prepare hybrid clones of Babesia canis and need not be used in the invention VII

6. Invention II is related to inventions VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in immunoaffinity chromatography methods for purifying antibodies and need not be used in the invention VIII.

7. Invention III is related to inventions IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in immunoaffinity chromatography [illegible]

8. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Concerning the burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The DNA database searches required by each of the sequences and the literature searches for each of the sequences, both of which are particularly relevant in this art, are not co-extensive and are much more important in evaluating the burden of search. Further, it is doubted that applicants would readily accept the rejection of one sequence by the application of art teaching another sequence. Clearly different searches and issues are involved in the examination of each group.

10. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.

9/22/03